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November 18, 2019

VIA ECF
Honorable Joel Schneider
United States Magistrate Judge
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, New Jersey 08101

Re: IN RE: VALSARTAN N-NITROSODIMETHYLAMINE (NDMA) PRODUCTS LIABILITY LITIGATION
Civil No. 19-2875 (RBK/JS)

Dear Judge Schneider:

Plaintiffs respectfully submit this letter brief in response to Defendants' letter Regarding "Macro" Discovery Issues ("Defs. Macro Ltr.") (D.E. 287).

I. PRELIMINARY STATEMENT

Defendants continue to stake out positions demonstrating that their ultimate goal is to obstruct legitimate requests and grind discovery to a slow crawl, inexplicably continuing to hide behind invalid objections. This phase echoes the core discovery phase, where Defendants took positions designed to deny or delay legitimate discovery. However, the mantra then – that Plaintiffs would obtain the broader categories of information in response to a detailed request for

documents – has been replaced by a request to cut off necessary discovery at this phase as well. This Court assured Plaintiffs that the broad discovery needed to establish this case would be compelled if needed, and that time has now come.

Defendants argue that Plaintiffs' requests are "unbounded" and "far-reaching" while simultaneously stonewalling Plaintiffs during meet-and-confers by not providing concrete positions on what parts of Plaintiffs' requests are objectionable and why, and which documents Defendants find unobjectionable and which documents Defendants will agree to produce as required by Rule 34. For example, Defendants criticize Plaintiffs for requesting generalized "risk assessment" and "evaluation" documents but fail to grapple with their disclaimers of any knowledge on meet-and-confers as to the types (and company-specific names) of documents their clients keep and maintain in these general areas.[1] Defendants' failure to provide concrete information about which documents Defendants *are* willing to produce, and on what timeline, hamstrings this process and leaves Plaintiffs with little room to explore logical compromises.

Defendants' mischaracterizations permeate their entire brief. In another example, Defendants portray Plaintiffs as seeking "all" foreign regulatory documents, which is obviously not accurate, and then take the position that Plaintiffs are entitled to "none" of the foreign regulatory documents. Plaintiffs have requested foreign regulatory documents related to the

[1] In a meet-and-confer regarding Requests for the Production of Documents ("RFPDs") related to the heart of this litigation – manufacturing – Defendants incredibly asked Plaintiffs to provide Defendants with a list of internal company documents identified in core discovery which Plaintiffs believed should be expeditiously produced. Defendants stated they needed this information to assist them in understanding *how their own client maintains documents in the ordinary course of business*. Nevertheless, Plaintiffs acquiesced and provided Defendants with a 7-page letter delineating hundreds of examples found referenced in Establishment Inspection Reports ("EIRs"). Plaintiffs cannot do more to assist with this process than they already have.

valsartan contamination, including those addressing testing data, inspections of facilities, correspondence with the foreign regulatory agencies regarding the recall (and associated testing), and submissions regarding the API manufacturing process (and the changes made therein). Moreover, Plaintiffs have not requested "all" foreign sales and marketing documents, only those regarding the communications and customer complaints related to the sale of valsartan API to other finished dose customers, and the pricing data associated with those API sales. Similarly, Plaintiffs have not requested "all" documents regarding finished dose manufacturing, and in an effort to resolve objections, Plaintiffs have asked Defendants to commit to produce a smaller subset of documents related to cGMP compliance, quality assurance functions, and bioequivalence studies but that effort at compromise remains unrequited.

Defendants are apparently determined to limit compromise, and instead advocate for substantial or complete invalidation of the discovery requests pursuant to baseless objections. Again, the strategy is clear and should be rejected at this significant juncture. Plaintiffs' discovery requests should be responded to, especially as narrowed by Plaintiffs.

II. LEGAL STANDARD

Despite all of Defendants' exhortations, nothing about the 2015 amendment to Rule 26 has created a fundamentally different framework for assessing the propriety of discovery in this case. *See N. Shore-Long Island Jewish Health Sys. v. Multiplan, Inc.*, 325 F.R.D. 36, 47-48 (E.D.N.Y. 2018) ("Rule 26(b)(1), as amended . . . constitutes a reemphasis on the importance of proportionality in discovery *but not a substantive change in the law*.'") (citations and alterations omitted) (emphasis added).

Defendants' stonewall of discovery is not justified by the Rules. Indeed, Rule 26(b)(1)'s proportionality mandate considers, among other thing, "the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." F.R.C.P. Rule 26(b)(1). These factors clearly favor Plaintiffs' position here. Defendants have control of all the critical information and documents, and Plaintiffs need these items in order to understand and build this case. The obstruction is multiplied in effect here, where much of the actionable conduct occurred overseas in China and India. Given the relative access of the parties to the witnesses, facts, and documents, Plaintiffs' requests, especially as narrowed below, are the efficient, proportionate, inexpensive and, thus, appropriate option.

III. PERTINENT BACKGROUND

First, the factual context as understood at present, has been twisted by Defendants. Defendants are not merely innocent bystanders, victims of circumstance who could have never known or contemplated that nitrosamine would form as a result of the cost-cutting manufacturing choices they made with respect to their "life-saving" drugs. Based on the information available at present, it appears that the unknown and unidentified so-called "ghost peaks" in testing representing unidentified artifacts in the API began appearing in the valsartan chromatography at ZHP's Chuannan API manufacturing facility at least as early as 2008. Ex. 1 (2018 Establishment Inspection Report ("2018 ZHP EIR")) (obtained by Plaintiffs pursuant to a FOIA request). Despite early knowledge of these highly suspicious unknown peaks,[2] ZHP failed to

[2] When finally confronted by the FDA in 2018 regarding ZHP's processes and procedures in place to identify unknown peaks in valsartan testing, Yinhua Tang, the Assistant Director of the

take the necessary steps to identify the cause of these concerning test results, and continued to make material modifications to its process, with the intended goal of "significant" cost reductions to allow them to "dominate the world market share." *Id*. at 25. In 2011, when ZHP completed the lab scale inquiry into its last cost-saving manufacturing process change, ZHP's "formal risk assessment" inquiry into whether this change might result in unintended chemical reactions or impurities consisted of one form document, comprised of check boxes, wherein departments could simply check "yes" or "no" regarding the process change. *Id*. at 23. The change in 2011 resulted in an onslaught of noticeable and documented quality issues, many of which went uninvestigated. Indeed, between 2016 to 2018, 22 batches of API were rejected and/or returned by customers because they failed to meet specifications and/or were presenting with aberrant testing. *Id.* at 8. Between January 22, 2016 to June 29, 2017 alone, there were 17 Out-of-Specification ("OOS") investigations regarding one particular batch of valsartan API. *Id.* at 29. These investigations were never adequately or successfully resolved. *Id.* This batch, it would later turn out, had been contaminated the entire time. *Id*. When confronted with these rejected, refused, and/or OOS batches, instead of conducting a root cause analysis, ZHP apparently re-processed the raw material[3] and sold it to other customers. *Id.* at 27-28.

At Mylan's valsartan finished dose facility in Morgantown, West Virginia, the FDA inspectors could not help but notice the full shredding bins located in the Quality Control division, the Quality Assurance division, the Environmental Health and Safety Division, and the

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Quality Control at ZHP informed the inspector that there was no written procedure beyond reporting it to a team leader. Ex. 1, (2018 ZHP EIR) at 17.

[3] ZHP would later admit to regulators that it was not possible to remove the impurity by reprocessing returned Valsartan API. Ex. 1, at 20.

Packaging and Manufacturing Divisions. Ex. 2 (2016 Form 483 for Morgantown Facility ("2016 Mylan Morgantown 483")) at 6. The original laboratory documents set to be shredded in these multiple bins were so voluminous that the FDA inspectors could not review them all. *Id*. Were that not troubling enough, FDA inspectors also noticed that the parameters of valsartan test samples had been altered after a test had already occurred. *Id*. The situation was no better at Mylan's Nashik, India Facility (another facility where Mylan manufactured valsartan finished dose). To start, FDA inspectors observed that Mylan's Empower software logged hundreds of data failures and errors. Ex. 3 (2016 Form 483 for Nashik Facility ("2016 Mylan Nashik 483")) at 6-7. These errors included, "connection to chromatography system lost" and "instrument malfunctions." *Id*. The failures were purportedly attributed to loss of power, loss of connectivity, and other associated errors. *Id*. Furthermore, because none of the data had been backed up to a redundant server, the chromatography data was apparently forever lost. *Id.* Even more damning, Mylan appeared to do absolutely nothing about the lost data. *Id*. ("No CAPA or investigation has been opened to address these incidents of '[p]ossible data corruptions or modification of file.' Data was lost, as it was not captured in a backup system.")

As for Hetero and Aurobindo, the Indian entities continue to refuse to participate actively in discovery, so Plaintiffs have yet to have an opportunity to probe their manufacturing processes.

Defendants argue that Plaintiffs are entitled to almost **none** of the above underlying facts.[4] Under Defendants' interpretation of the relevant scope of the case, discovery regarding

[4] The documents cited in Exs. 1-3 consist of FDA inspection documents obtained by Plaintiffs pursuant to FOIA requests, and/or that are publicly available on the internet as a result of FOIA

2008 so-called "ghost peaks" should be excluded because it is outside the "relevant time period" identified by the Defendants for discovery. To the extent a foreign market API customer returned batches of API because it did not meet specifications and was presenting with aberrant and unidentified peaks, Defendants inexplicably argue this information is not discoverable because it did not end up in any one plaintiff's pill in the United States. Of course, *all* evidence of contamination is relevant. And finally, Defendants argue that discovery of the FDA's observations in 2016 of ***altered valsartan testing***, mounds of laboratory documents to be shredded, and data failures in the Chromatography software should be excluded because it did not directly pertain to manufacturing of the valsartan active ingredient itself.

Defendants cannot be permitted to obfuscate and hide damaging discovery by baselessly resting on boilerplate relevance and proportionality objections, completely unsupported by fact or detail as to why the production would be burdensome or disproportionate under the Federal Rules.

IV. RESPONSE TO DEFENDANTS' "MACRO" DISCOVERY ISSUES

a. Foreign Regulatory Documents

Defendants' blanket attempt to shield *all* documents submitted to, or created by, foreign regulatory agencies should be rejected. Foreign regulatory discovery is critical here, where the manufacturers were in direct communication with these agencies regarding the issues at the heart of this litigation. Indeed, ultimately all of these agencies worked in concert to engineer a

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requests made by other individuals. These documents have been heavily redacted pursuant to the FDA's public release of information, and much of the drug information has been excised. Plaintiffs are entitled to the full, unredacted versions of these documents, which are in the Defendants' custody and control but have not been produced to Plaintiffs.

massive worldwide recall. To the extent relevant, all factual information exchanged with the foreign regulatory agencies should be produced.

There is evidence to suggest that Defendants were utilizing different manufacturing processes for valsartan depending on the country. *See* MYLAN-MDL2875-00030355-408, PRINSTON0075683-96. Because of these varying processes, communications with foreign regulatory agencies regarding the recall (and the associated testing conducted), as well as the formal regulatory filings regarding the API manufacturing process, clearly bear upon Defendants' notice, and the availability of an alternative feasible design to the manufacturing process. More fundamentally, inspection documents of the foreign facilities provide discovery regarding the Defendants' overall compliance with cGMPs. Plaintiffs should be afforded discovery[5] of the communications with foreign regulatory agencies regarding the contamination, recalls, regulatory inspection documents, and formal foreign regulatory filings as to the valsartan API manufacturing process.

i. **Communications with Foreign Regulatory Agencies Regarding the Recall are Obviously Relevant and Proportionate**

Defendants argue that because they provided authority for all foreign regulatory agencies to exchange information,[6] this necessarily "ensur[ed] that the information conveyed to regulators [was] consistent across the board." *See* Defs. Macro Ltr. at 8. First, Plaintiffs' cannot rely on

[5] Plaintiffs are willing to limit this discovery even further by narrowing the requests to a known list of foreign regulatory agencies, subject to a meet-and-confer with the Parties.

[6] Defendants' argument that the FDA requested access to other foreign regulatory agency submissions further supports Plaintiffs' position that these documents are clearly relevant. Indeed, the FDA clearly believed having access to the other testing and process information provided to foreign regulatory bodies would elucidate the FDA's own understanding of how the impurity formed in products that made their way into the US. Plaintiffs, and their experts, should be afforded this same opportunity.

Defendants' self-serving representation that their admissions and communications with individual regulatory agents were "consistent" – Plaintiffs are entitled to probe these admissions and compare them to the information provided to the FDA. These admissions would include Defendants' discussions with other foreign regulatory agencies regarding test results, their hypothesis as to the cause of the contamination, the extent of the contamination, and the health consequences of the contamination.

Additionally, because there is evidence to suggest that Defendants were utilizing different manufacturing processes for valsartan in different countries, as set forth above, Plaintiffs must review the testing results of each distinct manufacturing process to understand how those changes impacted the levels of impurity, the impurity profiles, and the risk assessments of the processes. Indeed, if one manufacturing process for valsartan API destined for the US was showing suspicious unknown peaks, whereas a different process for valsartan API destined for elsewhere was not, that would be highly probative of a Defendant's notice of a potential issue with the former.

i. **Foreign Inspection Reports Document Clearly Discoverable Underlying Facts**

Plaintiffs are entitled to discover evidence regarding Defendants' compliance (or non-compliance) with cGMPs at their valsartan manufacturing facilities. It defies logic that Defendants now attempt to argue that Plaintiffs are not entitled to discover foreign inspection reports, which document and memorialize an inspector's contemporaneous and present sense impressions and/or observations of Defendants' compliance (or non-compliance) with cGMPs.

In order to monitor overseas manufacturing, the FDA participates in a cost-sharing program with foreign governments (including Australia, Canada, Switzerland, Austria, the UK, Germany, Sweden, Denmark, Japan, Singapore and Italy) known as the Pharmaceutical Inspection Co-operation Scheme ("PIC/S").[7] Regulators in these countries work together to inspect facilities pursuant to shared standards and have regularly scheduled meetings to discuss their shared views on compliance with cGMPs. *See* Ex. 4, (FDACDER_0001171-77) (documenting a December 2015 PIC/S Meeting regarding data integrity guidelines to be used by industry, drafted in conjunction with officials at the FDA and officials from other foreign regulatory offices) (obtained by Plaintiffs pursuant to a FOIA request). Logically, it makes no difference whether the inspector who visited an overseas site was from Australia, Japan, the United Kingdom or the United States—the inspector would still have observed the manufacturing processes at issue and would be documenting their observations about Defendants' compliance (or non-compliance) based upon the same cGMP standards each and every regulatory inspector for PIC/S countries assents to follow. Indeed, inspectors from the PIC/S participating countries attend group trainings, on issues such as how to inspect for data integrity issues with workshops providing practical examples on how to inspect, which further demonstrates their shared understanding of cGMP compliance. Ex. 5, (FDACDER_0001187-89) (Obtained pursuant to Plaintiffs' FOIA Requests).[8] Taking Defendants' position regarding

[7] *See* "List of Participating PIC/S Countries," https://www.picscheme.org/en/members (accessed Nov. 12, 2019).

[8] That the foreign regulatory inspectors follow the same guidelines and principals regarding cGMPs completely undercuts Defendants' argument that foreign regulatory documents are not relevant to the extent that the standards between the countries are different. With respect to

foreign regulatory inspection reports (and communications related to those inspections) to its logical end would mean that two documents could detail similar data integrity issues which occur at the same valsartan manufacturing facility in two different years, but because one of those documents was authored by an Italian, Plaintiffs would not receive it. Furthermore, production of these documents (which are no doubt kept in a centrally located repository in each Defendant's regulatory affairs department) is a far more efficient outcome than requiring Plaintiffs to engage in protracted Letters Rogatory to obtain these obviously relevant facts.

ii. **Foreign Regulatory Submissions Regarding API Manufacturing are Relevant to Defendants' Notice and Alternative Feasible Manufacturing Process**

With respect to more formalized foreign regulatory submissions, *even after* the 2015 amendments to Rule 26, courts have held that these foreign submissions are relevant to the issue of whether Defendants were on notice. *In re Davol, Inc.*, No. 2:18-md-2846, 2019 WL 341909, at *2 (S.D. Ohio Jan. 28, 2019) (Ex. 16) (these materials are relevant "to the extent they contain information about what Defendants knew about the alleged risks associated with their . . . products, when they knew about those alleged risks, and whether those alleged risks were communicated to physicians and patients."); *Hodges v. Pfizer, Inc.*, No. 14-4855 ADM/TNL, 2016 WL 1222229, at *3 (D. Minn. Mar. 28, 2016) (Ex. 17) (explaining that "there is no relevance-based reason to so limit discovery—notice of the risks of [an adverse effect] could conceivably originate from any country"); *Adams v. Merck Sharp & Dohme Corp. (In re Incretin-Based Therapies Prods. Liab. Litig.)*, 721 F. App'x 580, 583 (9th Cir. 2017) (reversing,

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inspections and documentation regarding compliance with cGMPs, the standards are universal and consistent.

as an abuse of discretion, denial of plaintiffs' motion to compel production of the defendants' foreign regulatory files). [9]

While Defendants argue for an abstract, unsupported finding of irrelevance, they concede that foreign regulatory evidence "might shed light the defendant's notice or knowledge" [*sic*]. *See* Defs. Macro Ltr at 8. However, attempting to frame the entire question of notice in a myopic light most favorable to them, Defendants cite to a single document that they assert constitutes a "mountain" of proof that they "had no notice or knowledge of nitrosamine contamination before the summer of 2018." (*Id.*) However, this argument is fundamentally flawed. The question of when Defendants were on notice is not limited to when Defendants were on notice that their specific drugs contained NDMA. Rather, the question of Defendants' notice relates to multiple issues, for example when they were aware that their chromatography tests demonstrated unknown peaks, and aberrant testing results. Indeed, as discussed *infra*, an unknown peak investigated[10] by a customer of ZHP is the entire reason the contamination

[9] Defendants' frequent recitation of *In re Bard IVC Filters* is inapposite because, in that case, the plaintiffs were not seeking the foreign regulatory materials to prove notice. 317 F.R.D. 562, 566 (D. Ariz. 2016). Defendants' other cases primarily relate to the exclusion of evidence at trial and therefore have nothing to do with discovery disputes such as this one. *See Davol*, 2019 WL 341909 at *3 ("Defendants' argument that courts have often excluded evidence regarding foreign regulatory standards at trial is misplaced. Admissibility at trial does not determine relevancy for discovery purposes.") (citations excluded).

[10] For their part, ZHP admitted to FDA investigators that they had no written procedure to provide details on how to handle any type of abnormal, unknown, or unidentified peak. Ex. 1, 2018 EIR at 17. This further supports Plaintiffs' arguments as to the relevance of foreign inspection documents assessing the Defendants' cGMP measures, of which quality assurance procedures regarding all aspects of manufacturing, including the testing of aberrant and unknown peaks, is one such part.

became known.[11] *See* §IV.b.1 This proves that the existence, source and nature of the contamination was knowable the entire time.

Plaintiffs must know whether other foreign regulatory officials asked questions (and, most importantly, received answers) regarding any of the proposed manufacturing processes. These questions would include, for example, whether any valsartan products (or processes used to manufacture the products) were flagged or rejected at some point by a foreign regulatory agency because the product did not meet specifications or could not demonstrate that it had impurities that were below a certain threshold.

Additionally, foreign regulatory documents regarding API manufacturing will likely detail processes which diverged from the process used for US drugs, and how. Further, going to the question of notice, to the extent any of these processes *did or did not* result in nitrosamine formation, also bears directly upon the question of the source of the contamination.

[11] Defendants have repeatedly represented to the Court that testing to identify NDMA and NDEA only existed *after* the FDA innovated such a test. *See* Defs. Ltr. at 8 "Defendants had no notice or knowledge….before FDA developed novel testing methods to detect impurities at the levels observed in Defendants' valsartan"); *see, also,* June 26, 2019, CMC Tr. at 28:25-29:5 (Mr. Trischler: "The FDA actually developed what it called an innovative test to check for NDMA and NDEA, conducted some testing, notified manufacturers, asked manufacturers to conduct testing.") This is patently incorrect. ZHP's API customer observed an unknown peak in its own chromatogram testing of the raw API. Ex. 1 at 20. The API customer sent the samples to a third-party laboratory because of the suspicious peak. *Id*. The third-party laboratory identified it as a genotoxic impurity. *Id.* The API customer then presented their findings to ZHP, informing ZHP that the observed unknown peaks constituted "a genotoxic impurity." *Id*.

b. Foreign Sales and Marketing Materials

i. **Foreign Sales of API Are Relevant to Notice**

The Parties are before the Court, litigating this case, **because an API customer of ZHP's noticed something was aberrant with ZHP's product**. Ex. 1, (2018 ZHP EIR) at 7 (finding that a ZHP customer "identified a small unknown peak during residual solvent testing using a GC-FID"). This customer, alarmed by the presence of an unknown and unidentified peak, independently sent a sample of ZHP's API to a third-party laboratory, that then identified the unknown peak as NDMA. *Id.* Had this API customer not independently tested ZHP's API, *all* Defendants might still be selling their product, and all Plaintiffs might still be paying for and consuming pills tainted with carcinogens.

However, the above API customer was not the only API customer who noticed issues with Defendants' API product. Based on the limited discovery to date, it is clear that at least as to Defendant ZHP, several other customers had aberrant OOS results when testing ZHP's API product. Ex. 1, (2018 ZHP EIR) at 8 (the FDA notes that from 2016 to 2018 there were 22 batches of API which were rejected and/or returned by customers). Between January 22, 2016 to June 29, 2017 there were 17 Out-of-Specification ("OOS") investigations into a single batch of valsartan API which did not result in any conclusory findings. *Id*. at 29. In 2018, it would turn out this batch was actually contaminated with a genotoxic impurity. *Id.* Other ZHP customers returned valsartan API showing similar OOS findings on September 13, 2016. *Id.* at 46. Rather than investigate the API that a customer found unmerchantable, ZHP instead reprocessed the batch and sent it to other customers. *Id.* at 47.

Nevertheless, Defendants wish to arbitrarily limit discovery as to these key communications regarding API sales to *only* those customers who purchased API for finished dose products intended for the US Markets with approved ANDAs. First, this would necessarily limit discovery regarding API sales and marketing to *only* the Defendants in this litigation who obviously did not become aware of the contamination until the recall. Defendants purposefully do not mention this.[12] Second, this would preclude Plaintiffs from discovering information about whether other customers purchasing valsartan API (including US customers with unapproved or tentatively approved ANDAs, as well as foreign customers) were returning product or lodging complaints about unknown and unidentified peaks. It is entirely possible another customer, understanding the chemistry of the tetrazole ring formation process, additionally identified an unknown peak as possibly being a nitrosamine[13] and reported it to a Defendant. Indeed, as discussed *infra* ZHP had a customer who requested a specific process which did not result in nitrosamine contamination. *See* § IV(f)(ii).

Also as set forth above, there is evidence that Defendants were manufacturing different API using different processes, for different foreign markets. *See* MYLAN-MDL2875-00030355-

[12] Putting aside ZHP, as to the other non-API Manufacturers in this case (Mylan, Aurobindo and Hetero), by limiting API sales discovery only to their US customers, discovery would only entail their own vertically integrated finished dose manufacturing entities (with exception of the brief period of time Mylan sold API to Teva). And yet, Defendant Mylan refuses to produce any discovery whatsoever regarding their finished dose entities. *See infra* at § IV.c.i. This puts Plaintiffs in an untenable position.

[13] As soon as a customer presented ZHP with the information that their valsartan API had tested positive for NDMA, ZHP immediately knew what step in the process had created the NDMA and was so confident in this assessment that it did not even conduct subsequent tests to verify their hypothesis. Ex. 1, (2018 ZHP EIR) at 7 (ZHP telling an FDA inspector that it did not do subsequent test of their hypothesis because "everyone retrospectively agree[d]" about how it was formed.)

408, PRINSTON0075683-96. Such information also informs Defendants' constructive or actual knowledge that the manufacturing processes that resulted in the nitrosamine contamination were inadequate. Additionally, to the extent these country-specific processes involved more steps or different solvents to ensure fewer impurities, Plaintiffs are entitled to know how much it cost Defendants to make these API, and how much they sold these API for, as compared to what occurred with the API destined for the United States. This information is critically important for an assessment of economic damages, especially to the extent Plaintiffs seek disgorgement of profits. [14]

c. Finished Dose Manufacturing

As set forth in Plaintiffs' November 5, 2019 opening letter brief on macro discovery issues, Plaintiffs are clearly entitled to discovery not only of Defendants' valsartan API manufacturing facilities, but also of downstream finished dose, bottling, and labeling facilities. *See* D.E. 289 (Plaintiffs' Macro Letter Brief ("Pls. Macro Ltr.")) at 6-15. All such downstream facilities are subject to cGMP obligations. Indeed, as described above, it was a finished dose facility that identified the nitrosamine contamination in ZHP's valsartan pursuant to routine testing and quality assurance functioning as required by FDA regulations.

Recognizing the speciousness of their initial "API only" position, Defendants now concede that the only discovery that should be permitted into the finished dose manufacturing is "***to the extent*** finished dose manufacturers conducted testing on the API at issue …." (Defs.

[14] And the profits, were, indeed, significant. ZHP itself admitted that changes and shortcuts it made to its manufacturing process was to "save money" and that doing so allowed ZHP to "dominate the world market share." Ex. 1, (2018 ZHP EIR) at 25.

Macro Ltr. at 12 (emphasis added).)[15] Defendants' explicit admission emphasized above appears to concede that certain finished dose facilities may not have conducted testing. This is a case in point why broader discovery of these Defendants and their facilities is absolutely necessary.

i. **Discovery regarding cGMP Compliance and Inspections**

Under federal law (The Drug Supply Chain Security Act ("DSCSA"), 21 U.S.C. § 353 et seq.) and federal regulations (21 CFR Parts 210 and 211), all entities in the manufacturing chain of distribution have an obligation to comply with cGMPs concerning quality issues "impacting on the identity and purity of the product" and to have adequate quality controls with respect to "the testing and approval or rejection of….drug products[.]" *See also* 21 CFR § 211.22. The finished dose manufacturers[16] are undisputedly bound by the DSCSA and cGMP regulations. As explained by the FDA itself, cGMPs provide for systems that assure proper design, monitoring, and control of the manufacturing processes and facilities. Adherence to the cGMP regulations assures the identity strength, quality and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations.

[15] To the extent it is not abundantly clear, Plaintiffs are entitled to any and all communications occurring between Finished Dose Manufacturer Defendants and those entities from whom they obtained valsartan API regarding the API, as well as any testing, contamination and health risks associated with that API product. Defendants' position appears carefully crafted to exclude these communications. The Court should require Finished Dose Manufacturers (including those API manufacturers with Finished Dose Facilities) to produce all relevant communications between the Manufacturer and the entity from whom it purchased API.

[16] Plaintiffs include in their description of finished dose manufacturers those finished dose manufacturers who are also associated with an API manufacturer. Separate and independent obligations attach at each step. Simply because a finished dose manufacturer may procure API from an affiliated and/or vertically integrated facility does not absolve it of its legal requirements to ensure their products are safe, effective, and uncontaminated.

The discovery obtained to date combined with Defendants' own admissions strongly suggest rampant disregard of the very cGMPs designed to ensure quality control of the products passing through Defendants' finished dose facilities. Defendants' documented disregard of cGMPs at the finished dose level is highly relevant to establishing Defendants' actual or constructive knowledge, to establishing recklessness and violation of federal laws for negligence *per se*, establishing the right to recover punitive damages, for the creation of potential adverse inferences against certain defendants for efforts to falsely suggest compliance with cGMPs, and myriad other aspects of proof in this litigation. Plaintiffs are thus entitled to broad discovery regarding the finished dose manufacturers' overall compliance with cGMPs at these facilities. API Manufacturers, notably ZHP and Mylan, have refused to produce these documents (both in core discovery, and during meet-and-confers, arguing, in blanket fashion, that any discovery outside the API step that supposedly caused the contamination "exceeds the scope of discovery permitted under the Federal Rules of Civil Procedure.") *See* Mylan Response to RFPDs attached to Pls. Macro Ltr. at Ex. 2. Of course, to the extent the contamination predated the manufacturing process modification, Defendants' entire narrative is subject to question.

By admitting that finished dose API *testing* is relevant, Defendants necessarily admit that compliance with cGMPs is also relevant. Indeed, cGMPs are devised, implemented, promulgated and enforced because these best practices provide the best protection against adulterated products entering the market.[17] They are also designed to impose accountability in the unfortunate case

[17] For example, with respect to API procurement, industry best practices dictate that finished dose manufacturers should have their Quality Assurance team "perform offsite or onsite audit activity" including an evaluation of the API factory quality systems, deviations, CAPA, recalls, warning letters, reprocessing batches, annual reports…OOS, OOT[.]" Ex. 6, Article from the

when such products do reach consumers. These cGMPs require the implementation of quality assurance departments to fully investigate and analyze every aberrant test result. 21 CFR § 211.22 *et seq.* These cGMPs also require manufacturers to conduct due diligence into the entities from whom they source API, regardless of whether the API comes from a vertically integrated associated entity.

It is apparent that *some* finished dose manufacturer was able to determine there was something wrong with the adulterated API it was purchasing, because one such finished dose manufacturer *actually uncovered* the adulteration which has spawned this lawsuit. *See* Ex. 1, (2018 ZHP EIR) at 7. What differentiates this customer from the Finished Dose Manufacturers in this case, who did not discover the API they were using in their finished dose product was adulterated with a genotoxic impurity? The answer likely lies in cGMP compliance – or lack thereof.

No Defendant has argued more forcefully for the irrelevance of finished dose manufacturing cGMP compliance (or non-compliance) than Defendant Mylan. However, newly obtained publicly available inspection documents regarding some of the most recent inspections of the valsartan finished dose facilities lays bare the truth.[18] Furthermore, not only were the inspections relevant to valsartan by the explicit mention of valsartan in limited unredacted

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Pharmaceutica Analytica Acta (authored by, among others, an employee for Defendant Hetero Labs). Plaintiffs are entitled to know which, if any, of these quality assurance activities Finished Dose Manufacturers conducted.

[18] Because Plaintiffs received these FDA documents from a publicly available source, large portions of the documents, including the multitude of pages wherein the FDA discusses the rampant shredding of documents, have been redacted.

portions of the Form 483(s), but they document a repeated pattern of data manipulation, document destruction, test alteration and obfuscation.

For example, in 2016, an FDA inspector found that employees in the quality control laboratory at Mylan's Morgantown, WV finished dose manufacturing facility were altering sample sets "for significant changes." Ex. 2 (2016 Mylan Morgantown 483) at 6. This included altering the parameters of a ***valsartan HCTZ*** sample, including the dilution factor, sample ID, test ID, sample name, composite weight, and sample weight. *Id.* The inspector also observed that the Quality Unit maintained shredding bins in the Quality Control unit, the Quality Assurance unit, and the manufacturing areas, and these bins were found to contain laboratory records.[19] *Id.* Were this not enough, the inspector likewise found that raw APIs were being analyzed using "non-validated and non-verified analytical methods." *Id.*

With respect to chromatography testing (which Defendants themselves concede is a critically important test to this litigation), the FDA found that Mylan's software, Empower, was riddled with data failures, power failures, loss of connectivity and repeated and recurring errors, suggestive of rampant data manipulation. *See* Ex. 3, (2016 Mylan Nashik EIR) at 7 (errors with Empower included, "connection to chromatography system lost"). The FDA inspector noted "150 messages indicating "possible data corruption or modification of file" affecting 12 sequences, and that "data was lost, as it was not captured in the back-up system." *Id.* The FDA inspector further noted that Mylan did not open an investigation into these data failures. *Id.*

[19] In the publicly available version of the 483 obtained by Plaintiffs the entirety of the two-page list of Quality Assurance documents which were to be shredded was redacted, so Plaintiffs do not know if this list relates to valsartan. Defendant Mylan is the only entity who can provide Plaintiffs with unredacted versions of these documents.

Because Plaintiffs received these FDA documents from a publicly available source, many of the drug names (with the exception of one reference to valsartan HCTZ) have been redacted.

Plaintiffs are entitled to unredacted versions of these documents to understand cGMP compliance at finished dose manufacturing facilities. As such, Plaintiffs ask this Court for a clear and unequivocal order compelling Defendants Mylan and ZHP to produce inspection documents[20] related to the facilities that manufacture the finished dose versions of their products.[21]

ii. **Discovery regarding OOS results, deviation reports, and complaints**

Defendants have effectively conceded that finished dose manufacturing testing results and other reports of quality issues at these facilities are relevant and must be produced, yet still refuse to produce them. *See* Defs. Macro Ltr. at 12. The Court should resolve Defendants' contradictory positions by compelling such discovery here. Complaints regarding the quality of both API and finished dose product are also highly relevant because, again, such complaints are

[20] The three facilities Mylan uses to manufacture finished dose of valsartan have been inspected an astounding *17 times* since the drugs came on the market and *14 of those inspections warranted a written finding of non-compliance*. ZHP's finished dose facility has likewise been inspected 7 times since 2012, warranting 4 written findings of non-compliance. Defendants Mylan and ZHP have produced none of these documents.

[21] The API manufacturers' unjustified position that finished-dose manufacturing is not relevant must be remedied immediately. The selection of ESI custodians cannot be complete until Plaintiffs have an understanding of the possible custodians involved in these procurement and quality assurance capacities. Mylan and ZHP have refused to even provide organizational charts related to finished dose manufacturing. Plaintiffs asked for this information hoping it could negotiate these possible ESI custodians prior to the Court's ruling on this issue. Ex. 15, (requesting production of organizational charts for finished dose facilities to allow the Parties to "agree upon these custodians now and ensure that there are no additional delays in December when the Court clarifies the contours of discovery.") Defendants did not comply with this request. Defendants' obstinance (especially in the face of the other finished dose manufacturers' compliance) raises the likelihood that Defendants are engaging in gamesmanship solely to avoid turning over damaging documents.

suggestive of actual or constructive notice of the contamination and (at least some) Defendants' efforts to simply re-sell contaminated product that had been returned.

iii. **Discovery Regarding Bioequivalence**

In making the argument that they should be required to produce only one type of testing, (including stability testing), Defendants explicitly reserve the right to rely upon their bioequivalence testing submitted to the FDA regarding stability. *See* Defs. Macro Ltr. at 15. However, Defendants would deny Plaintiffs the opportunity to test the validity of that bioequivalence testing, or to analyze the underlying documentation in support of the testing located in the ANDA submission. Of course, bioequivalence testing is central and should all be produced.

The overall "sameness" of Defendants' valsartan products to the RLDs is highly relevant. For example, the Master Economic Loss complaint alleges that Defendants each breached a "duty of sameness" with regard to their valsartan products. The bioequivalence of Defendants' VCDs to their respective RLDs is also informative to Defendants' actual or constructive knowledge of quality control issues with regard to their products. This is especially so for Teva, and Mylan[22] who used vendors during the ordinary course of their business to conduct bioequivalence studies that were subsequently found to have fabricated bioequivalence data in support of ANDA applications.[23] The Court should compel Defendants to produce extensive bioequivalence discovery to Plaintiffs.

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[22] https://www.bloomberg.com/news/articles/2016-07-22/flawed-indian-studies-spur-eu-regulator-to-back-drug-suspensions.
[23] https://www.fda.gov/media/97424/download.

d. Testing and NDMA and NDEA Impurities

i. **Testing**

Despite having only produced a small subsection of limited core discovery documents, Defendants proclaim that the *only* testing relevant to this litigation is chromatography, and should only be limited to the tests related to the identification of NDMA and NDEA impurity (HPLC and GC). [24] While Plaintiffs do not likely need every type of test ever performed at every stage of the valsartan manufacturing process, at this point in time, Plaintiffs simply do not have enough information to limit or narrow testing requests in the manner Defendants suggest. Indeed, Plaintiffs informed Defendants of this during a meet-and-confer regarding their manufacturing and testing RFPDs.

In order to try to bridge this gap, Plaintiffs requested a list of all tests performed, and an exemplar of the results of each test, so that Plaintiffs could assess the universe of testing and focus on the tests most likely to yield significant data. Defendants have not agreed. Plaintiffs have also asked to see the internal company documents (including lists of OOS findings on tests, deviation reports, and complaints) that were provided to the FDA in the course of the inspections regarding this adulteration to help focus these requests. The fact that all Defendants are resisting production of directly relevant testing information sharply illustrates that the defense strategy is being applied across the board.

[24] It is ironic that Defendants are so confident in their claim that chromatography is the only relevant testing, when in every other area related to manufacturing, Defendants have asked Plaintiffs to explain to Defendants how Defendants keep their files, including asking Plaintiffs to provide Defendants with a list of *their own* internal company files.

ii. **Other Impurities**

Defendants appear poised to argue that discovery regarding other impurities (including, but not limited to, other genotoxic carcinogens) is not relevant because it is not the specific genotoxic impurity at issue in this case. To the extent Defendants are arguing that they should not be required to turn over evidence of other carcinogenic impurities, that argument is without merit, and has been addressed in Plaintiffs' opening papers. *See* Pls. Macro Ltr. at 20.

Furthermore, Plaintiffs will not blindly agree to any limitation excluding testing regarding residual solvents present in the valsartan API. Given the nature of the process, it may be possible that an early harbinger of an issue with the chemistry of the manufacturing process was the presence of excess residual solvent. Until Defendants provide Plaintiffs with an expedited production of internal documents (such as the documents provided to the FDA during their inspections of the facilities, which should have been provided with core discovery but was not), Plaintiffs cannot arrive at a position as to what other testing may be relevant.

e. Plaintiffs are Entitled to Discovery Regarding Health Issues Beyond Just Those Alleged in their Complaints

Fed. R. Civ. P. 26(b)(1) provides, "Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense…" In negotiating the personal injury Plaintiff Fact Sheet ("PFS"), Defendants demonstrated that one of their strategies for defending specific causation in this MDL was to conduct discovery into each Plaintiff's medical history. In doing so, Defendants requested a swath of information, including on a number of medical conditions that they will presumably claim could have contributed to a specific plaintiff's cancer. *See* PFS, § V. For this reason, to the extent Defendants have received

reports, conducted studies, inquiries, or investigations that shed light on the health risks posed by the contamination, and the relevance of these other conditions included in the PFS as they relate to valsartan, any injury alleged by any plaintiff in this MDL, and/or any of the contaminants in this litigation, Plaintiffs should be entitled to discovery regarding this information.

In conjunction with this, to the extent any of the conditions asked about by Defendants in the Plaintiffs Fact Sheet are indicative of early signs of cancer, this is all the more reason for Defendants to provide information relating to these conditions during discovery, as this information—whenever it was received—also should have placed Defendants on notice that many of their consumers were exhibiting early signs of cancers while taking their drugs.

i. **Plaintiffs' Discovery Requests are Narrowly Tailored in that they are already Confined to both the Products at Issue in this MDL, as well as the Contaminants at Issue**

Each discovery request cited by Defendants in Section 5 of their brief is already confined to the relevant issues being litigated in this MDL: valsartan, the contaminants at issue, and the adverse health effects associated with them. In listing all the allegedly applicable Requests for Production, Defendants failed to find any which did not already contain these limiters. Therefore, any concerns Defendants expressed about Plaintiffs allegedly attempting to develop new claims or straying beyond the scope of the litigation (*see* Defs. Macro Ltr. at 18) are unfounded.

Furthermore, with regard to the requests pertaining to studies or investigations, Defendants, as manufacturers of generic drugs, have repeatedly emphasized that they have far fewer investigation and study obligations than manufacturers of brand name drugs have. In light of this and the fact that these requests are already confined to the products, contaminants, and

issues in the above-captioned MDL, these requests fall squarely within the contemplated confines of Rule 26 and the scope of discovery here.

ii. **Evidence of Other Injuries Stemming from Contamination Goes to the Issues of Notice and General Negligence**

Discovery into other health effects caused either by valsartan and/or the contaminants at issue in this MDL is relevant to the issue of notice. Defendants' attempt to limit discovery to only those cancers which have presently been alleged by Plaintiffs represents a misconstruction of the Federal Rules of Civil Procedure, as well as an ignorance of the bigger picture.

Defendants themselves admit that the contamination issue stemmed from issues with the manufacturing process that went allegedly undetected for years. *See* Defs. Macro Ltr. at 4. However, to the extent Defendants contend that they did not and could not have known of the presence of nitrosamines and other contaminants in their raw API or in the finished doses they produced, any reports made to them, investigations conducted (or not conducted), studies, or inquiries relating to other adverse health effects caused by their drugs should have placed Defendants on notice that they had larger problems with their products.

f. Discovery Should Commence on a Date Prior to the Defendants' First Regulatory Filing

Logically, Plaintiffs ask this Court to allow for discovery commencing on a date prior to Defendants' first regulatory filing (be it an Abbreviated New Drug Application ("ANDA") or Drug Master File ("DMF")) with the FDA. The most logical date is the date on which the defendant in question began to develop the manufacturing process for valsartan, as creation of the process must have implicated all aspects of the process, the solvents to be used, and the quality assurance analysis of potential risks.

i. **Defendants Began Preparing to Launch their Valsartan Drugs Almost Two Decades Ago**

On June 18, 1997, Novartis Pharmaceuticals filed a patent for valsartan. Ex. 14, (Novartis Valsartan Patent). This drug molecule, which would later go on to be sold by Novartis under the brand names Diovan and Exforge, resulted in a billion-dollar market. Understanding the importance of filing an ANDA application for generic versions of these two drugs, with a specific eye to becoming the *first* company to file a substantially complete generic ANDA, generic manufacturers (including Defendants), began the process of developing not only the formulation of the finished dose of the drug, but the chemical synthesis of the active pharmaceutical ingredient, as soon as they could.

In order to prepare the regulatory documentation required by the FDA to seek approval (be it tentative, or otherwise) of their products, Defendants, very early on, began engaging in concerted research and development activities necessary to have the science in place prior to these FDA submissions. Evidence of these research and development activities, which occurred in the early 2000s, include filing patents covering their own methodologies for the synthesis of valsartan in the United States and abroad. [25] As part of these research and development activities, Defendants would have been deliberating on the choice of solvent, the choice of catalyst, the risk-benefit profiles associated with these selections, researching the process patented by

[25] Defendants in this litigation began filing patents to cover the synthesis of the valsartan active ingredient beginning as early as 2004. *See* Ex. 7, Teva's April 21, 2004 Patent Application. Other Defendants followed suit, including Aurobindo, Ex. 8, (who filed an application on June 29, 2007), and Mylan, Ex. 9 (whose predecessor Matrix Labs filed an application on June 26, 2008).

Novartis, assessing the cost of manufacture associated with the processes, and conducting lab-scale manufacturing and testing of a variety of processes.

Nevertheless, Defendants argue that discovery should be limited to a much narrower time period, beginning either when their drug actually launched onto the US markets (or, in the case of Defendant ZHP, when they made their **final** change to their manufacturing process). By so narrowly focusing the scope in this manner, Plaintiffs would be completely deprived of understanding the development of the manufacturing process, starting from first conception of the process, through all the permutations of the process, including the lab scale results of these permutations and modifications with any associated risk assessments. Discovery into the entirety of the process strikes directly at the heart of the question as to whether Defendants were on notice that their manufacturing changes were significantly and materially impacting the impurity profile of the molecule, and whether they conducted the necessary and required risk assessments into these changes. Any earlier risk assessments would likewise inform upon whether any later risk assessments conducted by Defendants were sufficient.

Also, it is likely that few documents dating back to when each Defendant first developed its manufacturing process still exist, given their vintage. This would sharply reduce the purported burden for Defendants, if any.

ii. **ZHP**

Discovery regarding Defendant ZHP should commence on a date prior to September 26, 2007. In September of 2007, ZHP filed its first DMF application to the FDA for a manufacturing process for valsartan API, which would later go on to be known as DMF No. 020939, or Process I. *See* PRINSTON00078567. After filing this first DMF to the FDA, on

January 1, 2010, ZHP filed a *second* application to the FDA for a *second* process for the manufacture of Valsartan under DMF No. 23491, which would be known as Process II. *See* PRINSTON00073120. According to ZHP, Process II would later go on to be the process which resulted in the formation of NDMA and NDEA, while the earlier process (Process I) did not create nitrosamines. Ex. 1, (2018 ZHP EIR) at 8. If the Court were to adopt ZHP's position that discovery as to manufacturing should only commence upon the date of the last 2011 manufacturing change, Plaintiffs would not only be denied the opportunity to understand the research and development which occurred prior of both DMFs but would also be denied the opportunity to probe the deliberative process conducted by ZHP in determining why to change from Process I (which did not have potential to form nitrosamines) to the process that resulted in nitrosamines. This obviously relevant discovery would include: what risk assessments were conducted in contemplating this change, whether this change resulted in a materially different impurity profile, why the company decided to file an entirely new submission to the FDA regarding the changes that occurred between Process I and Process II, and what were the justifications and motivations for changing the initially filed (non-nitrosamine forming) process.[26] Furthermore, evidence suggests there were actually finished dose manufacturers who selected the first (non-nitrosamine forming) process instead of the subsequent (nitrosamine forming) process. *See* Ex. 1 (2018 ZHP EIR) at 19 ("Process I was a customer specific process"). Plaintiffs are entitled to know why this customer opted for Process I.

[26] Indeed, during an inspection with the FDA in 2018 as a result of the contamination, ZHP's Executive Vice President, Mr. Jun Du, admitted to FDA officials that ZHP's motivation for making manufacturing changes to its valsartan API manufacturing process was "to save money." Ex. 1, (2018 ZHP EIR) at 25.

iii. **Mylan**

Discovery regarding Defendant Mylan should commence on a date prior to August 16, 2006. On this date, Defendant Mylan filed its first ANDA application to the FDA for the finished dose formulation of valsartan. *See* MYLAN-MDL2875-00006228. Plaintiffs should be afforded the opportunity to discover the entire development of the manufacturing process, including how Mylan selected the API it planned to use in that 2006 submission, and any quality assurance due diligence conducted in selecting that API. Further, Plaintiffs are also entitled to discover Mylan's quality assurance functions prior to drug launch as they relate to procurement of materials used in the manufacture of valsartan API. Indeed, in a Warning Letter sent by the FDA a mere 13 days ago, the FDA documented a litany of compliance issues with Mylan's procurement and use of solvents in their API manufacturing. Ex. 10 (November 5, 2019 Warning Letter). At issue for the FDA was Mylan's grossly inadequate quality assurance functions related to processes implemented to recover solvents, the due diligence used when selecting specific vendors to procure recovered solvents, and the storage facilities used for those recovered solvents. *Id.* If the Court were to accept Mylan's position that discovery is only appropriate as of the date the drug launched on the US markets, Plaintiffs would be denied discovery regarding all of the necessary preparations made in order to have those sufficient quantities of finished dose product stocked and on shelves in pharmacies by the launch date – including the development and implementation process followed by each entity to get to the manufacturing starting point. It would also deny Plaintiffs the opportunity to probe, more critically, what internal risk assessments were conducted regarding the use of recovered solvents and the solvent recovery processes, whether recovered solvents were used in batch testing that

was submitted to the FDA in support of their regulatory filings (and, to the extent batch testing was conducted using only fresh solvents, why that was the case), and whether Mylan conducted the appropriate due diligence in selecting vendors for raw materials and recovered solvents.

iv. **Teva**

Discovery regarding Defendant Teva should commence at some time prior to January 7, 2005. This is the day that Teva filed a substantially complete ANDA application with the FDA. Ex. 11, (Letter from Teva GC filed in support of a Citizen's Petition regarding Valsartan). Indeed, compared to the other Finished Dose Manufacturer Defendants in this case, Teva presents an interesting wrinkle insomuch as it appears Teva was contemplating manufacturing its *own* valsartan API as early as 2006. *See* Ex. 7, (Teva Patent). Were this not enough, Teva's status as the second ANDA filer after the first-filer (Ranbaxy Laboratories) provided Teva with incentive to continually conduct research and development in preparation that it might launch onto the market as soon as practicable. Teva went so far as to argue that Ranbaxy should be denied its first-filer status because of their "inadequate control measures for insuring the integrity of data." Ex. 11 at 3. Plaintiffs should be afforded the opportunity to probe Teva's actual or constructive knowledge on the potential formation of impurities (including nitrosamine impurities), which can be accomplished by understanding what process Teva was contemplating for its own API manufacture, and what impurities it believed could form as a result of that process. Plaintiffs should also be allowed to discover information regarding Teva's investigation into Ranbaxy's data integrity issues and use of tainted data, which it discussed at length in its filing to the FDA. *Id.*

Furthermore, Teva first obtained Valsartan API from Mylan, before switching to Defendant ZHP. Ex. 12 (TEVA-MDL2875-00004075). However, contemporaneous with these decisions regarding API sourcing, in 2013, Teva's President and CEO made comments while participating in the European Association of Pharmaceutical Full-line Wholesalers conference that the prices charged by Indian and Chinese drug companies for the products demonstrated that these manufacturers were "cutting corners" and consumers would never "sit on a plane if [they] thought the parts were coming from a dodgy factory somewhere … [s]o why do we accept this for medicines?" Ex. 13 (Article from Business Standard). Plaintiffs are entitled to discovery as to what due diligence Teva conducted when a) declining to manufacture their own API, b) determining from whom they might purchase valsartan API c) deciding to purchase valsartan API from Defendant Mylan, and d) the quality assurance controls in place which guided how to make these decisions. Much of this activity occurred well before Teva's proposed date of January 1, 2013.

v. **Torrent**

Discovery regarding Defendant Torrent should date back to some time prior to June 29, 2009. This is the day that Torrent filed an ANDA application with the FDA. *See* TORRENT-MDL2875-00002226. Prior to obtaining API from ZHP, Torrent had obtained API from another company. *See* TORRENT-MDL2875-00002095. If discovery is arbitrarily limited to the date their product actually launched on the market, Plaintiffs will be denied all the discovery regarding why they decided to switch to ZHP for procurement of valsartan API, what due diligence they did in deciding to purchase valsartan API from ZHP (including any on-site or offsite visits of the facility, any review of OOS and deviation reports, and the like) and any

testing of valsartan API samples. All of this activity occurred well before the date the drug product was actually in the United States market.

vi. **AuroLife**

Because Plaintiffs have yet to receive discovery regarding Aurobindo Ltd. (the Indian Entity who continues to be unrepresented in this litigation), Plaintiffs do not know the date on which the Indian entity filed its DMF for Valsartan API. Plaintiffs' default position is that discovery as to all of these entities should begin at some time prior to the filing of the API DMF was filed, when the manufacturing process began to be developed. However, in the absence of that information, and at the very latest date, Discovery regarding AuroLife and Aurobindo USA (as finished dose manufacturers) should begin at some time prior to June 19, 2010. This is the date by which the US entities submitted their ANDA submission to the FDA.

i. **Hetero and Camber**

Defendants' brief does not even mention proposed start dates for Hetero and Camber. Consistent with the above, the discovery start dates for these Defendants should also be when each of the Hetero Labs Ltd., and Hetero Drugs[27] began to develop their manufacturing processes.

[27] Two of the four API manufacturers (Hetero Drugs d/b/a Hetero Labs Ltd., and Aurobindo Pharma) are not yet actively participating in this litigation because they contend they are separate entities and have demanded Plaintiffs serve them via Hague Convention proceedings. Because of this schism within the Defendant Groups, Plaintiffs request that the Court issue a ruling that is also applicable to these entities, finding that whatever ruling the Court issues related to the Macro discovery issues is equally applicable as to these entities when they formally enter the case.

V. CONCLUSION

For the foregoing reasons, Plaintiffs request that the Court deny Defendants' motions, and compel Defendants to produce the full scope of requested discovery.

Respectfully,

ADAM M. SLATER

AMS/lat